REMARKS

Claims 1, 5, 6, 8, 12, 13, 15-18, 20-23, 31, 32, 34-37, 50 and 54-57 are pending in the present application. Claims 8 and 50 are canceled herein without prejudice to Applicant's right to prosecute the subject matter of this claim in a related application. Claims 1, 18, 31 and 34 are amended herein to recite that the claimed cytotherapeutic units comprise at least 1% $CD34^+$ cells. As pointed out in the pending Office Action at page 4, support for this amendment is found in the application as published at least in Example 1. *See, e.g.*, paragraph [0040]. Claims 1, 18, 31 and 34 are also amended herein to no longer specify that the recited $CD34^-$, $OCT\text{-}4^+$ and $SSEA3^-$ cells are "isolated from placental perfusate." Upon entry of this response, claims 1, 5, 6, 12, 13, 15-18, 20-23, 31, 32, 34-37 and 54-57 will be pending in the application.

Entry of the claims under 37 C.F.R. § 1.116(b)(1) and (b)(2) is respectfully requested, because the claims are presented in better form for allowance or appeal, and because claims have been canceled, yielding fewer claims than were previously pending. Moreover, the amendments presented herein do not require additional searching because any potentially material documents would have been identified during a search of "at least 100 $CD34^+$ cells," as recited in the previous claims, or during a search of "$CD34^-$, $OCT\text{-}4^+$, $SSEA3^-$" cells, as presented in the previous Amendment.

The Rejection Under 35 U.S.C. § 112, First Paragraph Should Be Withdrawn

Claims 1, 5, 6, 8, 12, 13, 15-18, 20-23, 31, 32, 34-37, 50 and 54-57 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking sufficient written description and constituting new matter. *See* Office Action at pages 3-10. As noted above, claims 8 and 50 have been canceled herein without prejudice. The Office Action contends that the specification does not disclose cytotherapeutic units comprising, *inter alia*, $CD34^-$, $OCT\text{-}4^+$ and $SSEA3^-$ cells isolated from placental perfusate. *See, e.g.*, page 4, lines 4-7 and 14-17; page 5, lines 7-10; and page 9, second paragraph. Although Applicant disagrees, for reasons already of record, and without conceding the correctness of the rejection, claims 1, 18, 31 and 34 are amended herein to no longer specify that the recited $CD34^-$, $OCT\text{-}4^+$ and $SSEA3^-$ cells are "isolated from placental perfusate." As such, this basis for the rejection is moot.

The written description requirement is satisfied where the application "clearly convey[s] the information that an applicant has invented the subject matter which is claimed" and "put[s] the public in possession of what the applicant claims as the invention." Manual of Patent Examining

Procedure (MPEP), Eighth Edition Incorporating Revision No. 6, § 2163, at page 2100-172 (citing *In re Barker*, 559 F.2d 588, 592 n.4 (C.C.P.A. 1977) and *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998).

Applicant respectfully points out that the rejection, with respect to either the rejected claims or the amended claims, is legally insufficient because it provides no evidence or reasoning as to why a person skilled in the art "would [not] be able to envision the specific combination of $CD34^-$, $OCT\text{-}4^+$ and $SSEA3^-$ cells . . . and . . . $CD34^+$ cells, from the instant specification." Office Action at page 5. "The Examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." Manual of Patent Examining Procedure, Eighth Edition Incorporating Revision No. 6 ("MPEP"), § 2163.04, page 2100-187, citing *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976); *see also Ex parte Sorenson*, 3 U.S.P.Q.2d 1462, 1463 (B.P.A.I. 1987); *see also* MPEP § 2162.03(III)(A) at page 2100-185. The present Office Action provides no such required evidence or reasoning, instead only conclusorily asserting that the specification allegedly does not describe the presently claimed embodiment. As such, the rejection is improper and should be withdrawn. Nonetheless, Applicant presents the following remarks.

The Office Action, at the bottom of page 4 and on page 10, acknowledges that the specification provides support, at least in Examples 1 and 2, for cytotherapeutic units comprising at least 1% $CD34^+$ cells. As noted above, claims 1, 18, 31 and 34, from which the remaining claims ultimately depend, have been amended to specify that the claimed cytotherapeutic units comprise "at least 1% $CD34^+$ cells," corresponding to subject matter that the Office Action indicates is disclosed in the application. As such, the rejection, with respect to the recitation of "at least 100 $CD34^+$ cells," is moot. A person of skill in the art would therefore readily be able to envision, from the specification, a cytotherapeutic units comprising at least 1% $CD34^+$ cells, as recited in the amended claims.

The specification also teaches that a cytotherapeutic unit can comprise more than one type of potent cell. *See, e.g.*, paragraphs [0040], [0043], [0047] and [0048], and Examples 1 and 2 of the published application. Moreover, the specification clearly teaches that a cytotherapeutic unit that comprises more than one type of potent cell can comprise at least 1% $CD34^+$ cells. *See* Examples 1 and 2. Such a cytotherapeutic unit would, of course, necessarily comprise $CD34^-$ cells. One of skill in the art, reading the present specification, would also readily appreciate that

such $CD34^-$ cells can include cells that are also "one or more of $CD10^+$, $CD29^+$, $CD34^-$, $CD38^-$, $CD44^+$, $CD45^-$, $CD54^+$, $CD90^+$, $SH2^+$, $SH3^+$, $SH4^+$, $SSEA3^-$, $SSEA4^-$, $OCT\text{-}4^+$ and $ABC\text{-}p^+$." *See* paragraphs [0012] and [0022]. Thus, a person of skill in the art would readily be able to envision a cytotherapeutic unit that comprises at least 1% $CD34^+$ cells and $CD34^-$ cells with all or any subset of these markers, including $CD34^-$, $OCT\text{-}4^+$ and $SSEA3^-$, as recited in claims 1, 18, 31 and 34.[1]

Thus, as explained in detail above, the specification clearly describes the claimed cytotherapeutic units, *as a whole*, in satisfaction of 35 U.S.C. § 112, first paragraph. As such, the claimed invention is clearly described in the specification, and the claims comprise no new matter.

To the extent that the rejection is based on a requirement that the claimed embodiments be set out exactly in the specification, Applicant respectfully reminds the Examiner that the specification is not required to disclose every embodiment of an invention *in haec verba* in order to satisfy the written description requirement. *See* M.P.E.P. § 2163.03 at page 2100-175, left column. Nor is the specification required to exemplify the recited embodiments. "As explained by the Federal Circuit, '(1) examples are not necessary to support the adequacy of a written description; (2) the written description standard may be met . . . even where actual reduction to practice of an invention is absent . . .'" M.P.E.P. at § 2163, page 2100-179, citing *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006); *see also LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (no examples necessary for written description); *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005) ("The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes," wherein the genes were novel combinations of known DNA segments).

Finally, the Office Action contends that, in the response to the previous Office Action, "arguments that individual components of the base claims are described in the instant specification do not address the rejection for new matter which is directed not at individual pieces of a potential claim embodiment but at the claimed invention as a whole." Office Action at page 10. Applicant demonstrates herein that the subject matter of the amended claims, *as a whole*, is fully supported

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[1] Applicants respectfully point out that, with respect to the Office Action's characterization, at page 3 and at page 5, of the cells recited in claims 54-57, each of these claims recites cells having exactly the same markers, *i.e.*, $CD10^+$, $CD29^+$, $CD34^-$, $CD38^-$, $CD44^+$, $CD45^-$, $CD54^+$, $CD90^+$, $SH2^+$, $SH3^+$, $SH4^+$, $SSEA3^-$, $SSEA4^-$, $OCT\text{-}4^+$, and $ABC\text{-}p^+$.

by the present specification. Applicant notes that, in establishing support for the invention *as a whole*, Applicant must necessarily discuss support for the components of the invention.

Thus, for at least the above reasons, the specification of the present application describes the cytotherapeutic units, as claimed in amended claims 1, 18, 31 and 34 in accordance with 35 U.S.C. § 112, first paragraph. As a result, the claims do not comprise new matter. Applicant respectfully submits that, because the rejection was directed to the independent claims, that the remaining rejected claims, each of which ultimately depends from one or claims 1, 18, 31 or 34, are described in the specification in accordance with 35 U.S.C. § 112, first paragraph, as well. Applicant respectfully requests that this rejection of the claims be withdrawn.

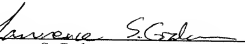
CONCLUSION

Applicant respectfully requests that the present remarks be made of record in the file history of the present application. An early allowance of the application is earnestly requested. The fee for a one month extension of time is estimated to be $130.00, and will be paid at the time this paper is filed by EFS-Web. Although Applicant believes that no other fee is due for the filing of this Amendment, the Commissioner is hereby authorized to charge any fee(s) deemed to be due, or to refund any overpayment, to Jones Day Deposit Account No. 503013, referencing our number 501872-999494.

The Examiner is invited to contact the undersigned with any questions concerning the application.

Respectfully submitted,

Date: August 3, 2009



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